IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

GEORGANN OGLESBY and STEPHEN OGLESBY,	§	
	§	
Plaintiffs,	§	
	§	
VS.	§	**CIVIL ACTION NO. SA-20-CV-1267-FB**
	§	
MEDTRONIC, INC., MEDTRONIC USA, INC. and INTEGRA LIFESCIENCES CORPORATION,	§	
	§	
Defendants.	§	

ORDER ACCEPTING REPORT AND RECOMMENDATION OF UNITED STATES MAGISTRATE JUDGE

Before the Court are the Report and Recommendation of United States Magistrate Judge filed on January 6, 2023 (docket #161); Plaintiffs' Objections to Magistrate Judge Henry J. Bemporad's Report and Recommendation filed on January 20, 2023 (docket #166); Joint Response to Plaintiffs' Objections to Magistrate Judge Henry J. Bemporad's Report and Recommendation filed on February 3, 2023 (docket #167); and Plaintiffs' Reply to Defendants' Response to Objections to Magistrate Judge Henry J. Bemporad's Report and Recommendation (docket #168). Also before the Court is Plaintiffs' Georgann Oglesby's Motion for Leave to File Exhibit 4 and Exhibit 5 of Plaintiffs' Reply to Defendants' Response to Objection to Magistrate Judge Henry J. Bemporad's Report and Recommendations Under Seal (docket #169) in order to preserve confidential documents produced by the Defendants. The Court finds the motion has merit and should be granted. Therefore, IT IS HEREBY ORDERED that Plaintiff's Motion for Leave to File Exhibit 4 and Exhibit 5 Under Seal (docket #169) is GRANTED such that these Exhibits will be sealed and remain under seal unless otherwise ordered by this Court.

Where no party has objected to a Magistrate Judge's Report and Recommendation, the Court need not conduct a de novo review of them. *See* 28 U.S.C. § 636(b)(1) ("A judge of the court shall

make a de novo determination of those portions of the report or specified proposed findings and recommendations to which objection is made."). In such cases, the Court need only review the Report and Recommendation and determine whether they are either clearly erroneous or contrary to law. *United States v. Wilson*, 864 F.2d 1219, 1221 (5th Cir.), *cert. denied*, 492 U.S. 918 (1989).

On the other hand, any Report or Recommendation to which there are objections requires de novo review by the Court. Such a review means that the Court will examine the entire record, and will make an independent assessment of the law. The Court need not, however, conduct a de novo review when the objections are frivolous, conclusive, or general in nature. *Battle v. United States Parole Commission*, 834 F.2d 419, 421 (5th Cir. 1987).

As set forth in the Report, Defendants are seeking summary judgment on Plaintiffs' claims for strict liability manufacturing defect, negligence, and negligent failure to warn. Plaintiffs also assert the doctrine of *res ipsa loquitur* and are seeking punitive damages and loss of consortium damages for Plaintiff Stephen Oglesby. Based on his analysis, Magistrate Judge Bemporad concludes that summary judgment should be granted as to: (1) Plaintiffs' strict liability manufacturing defect claim "[b]ecause Plaintiffs have not presented competent evidence of a specific manufacturing defect that led to the alleged injuries"; (2) Plaintiffs' negligence claims, including the *res ipsa loquitur* theory, because " Plaintiffs have failed to show a manufacturing defect [and] [a]bsent a specific defect, these claims like the strict liability claims also fail; and (3) Plaintiffs' failure to warn claim because there is no evidence that the treating physician, Dr. West, "'would have read or encountered'" an adequate warning. Report, docket #161 at pages 6, 7, and 9.

Plaintiffs in their objections disagree with Magistrate Judge Bemporad's analysis and recommendations to this Court as to their strict liability manufacturing defect and negligence claims only and have not objected to the dismissal of their failure to warn claim. With respect to the strict

liability and negligence claims, Plaintiffs objections are as follows:

1. "The Magistrate Judge erroneously concluded that Plaintiff proffered no evidence of a manufacturing defect when Plaintiff presented clear evidence that the Durepair device disintegrated when it was not designed to do so";
2. "Plaintiffs presented evidence that sufficiently ruled out other causes";
3. "The Magistrate Judge's report suggests that it wrongly required Plaintiffs to prove their case by a preponderance of the evidence, rather than demonstrate the existence of a fact question; and"
4. " The Magistrate Judge impermissibly engaged in the weighing of evidence in coming to its [sic] conclusions when it [sic] was supposed to consider all evidence in the light most favorable to Oglesby."

Plaintiffs' Objections, docket #166 at page 1. In their Joint Response, Defendants contend:

1. "Magistrate Judge Bemporad properly found the Plaintiffs' 'proof' of 'product failure or malfunction'" did not constitute "'competent evidence of a specific manufacturing defect,'" because "Texas law clearly defines a manufacturing defect as a deviation in 'construction or quality' from a product's 'specifications or planned output' that renders the product 'unreasonably dangerous,'" and "[t]o prevail on any manufacturing defect claim, a plaintiff must identify a '*specific defect* by competent evidence and rule out other possible causes of the damage.'" Defendants' Response, docket #167 at page 4. Defendants explain that because of this "'specific defect' requirement, a factfinder 'may not permissibly speculate that a defect existed on the basis of *product failure alone*.'" *Id.* at pages 4-5. "Far from identifying a 'specific defect'" in Defendant Integra's manufacturing process, Defendant maintains "the evidence here shows that

the lot of Durepair devices containing Plaintiff's patch met all manufacturing specifications before leaving Integra's facility." *Id.* at page 5. Specifically, Defendants point to their expert, Dr. Collin Stabler, who found "'no evidence that the released implants were not manufactured appropriately and no evidence [the subject lot of Durepair devices] was manufactured not in conformance with Medtronic's specifications.'" *Id.*

2. Magistrate Judge Bemporad did not err by refusing to allow Plaintiffs to rely solely on the failure of the Durepair device as circumstantial evidence of the defect in support of their strict liability claim and *res ipsa loquitur* evidence in support of their negligence claim because: "(1) the Durepair device was stored at Dr. West's hospital – outside of Defendants' control – for eight months before implantation; (2) the Durepair device was modified by Dr. West and/or his team just before implantation; and (3) the Durepair device was under the exclusive control of multiple entities prior to its alleged failure." *Id.* at pages 6-7.

3. Magistrate Judge Bemporad did not, contrary to Plaintiffs' assertion, evaluate the testimony of Plaintiff's expert, Dr. Rasty, under the preponderance of the evidence standard, but instead correctly determined that because Plaintiffs' expert could not determine whether the disintegration was caused by a manufacturing defect in the Durepair or the sealant applied to the Durepair by the surgeon prior to insertion into Ms. Oglesby, or both, there was legally insufficient evidence of a manufacturing defect. Moreover, Plaintiffs' claim there is a genuine issue of material fact because of the conflict between Dr. Rasty's first affidavit versus his second affidavit and deposition testimony is also without merit because Plaintiffs may not create a disputed

issue of material fact based on the first affidavit which was disavowed by Dr. Rasty in his deposition testimony and superseded by his second affidavit. Defendants explain further that Dr. Rasty confirmed in his deposition that he could not say the failure of the Durepair device was most likely caused by a manufacturing defect as opposed to the application of the sealant nor could he "diminish the probability of one compared to the other." *Id.* at page 13. Because Dr. Rasty could not find the "most likely cause" of device failure, Magistrate Judge Bemporad was correct to conclude this testimony was speculation and would be of no assistance to a jury by explaining, "'[w]hen the plaintiff's own evidence shows an equally likely alternative cause of the alleged damages, a manufacturing defect is not shown by a preponderance of the evidence.'" *Id.*

4. Magistrate Judge Bemporad also did not err in discounting the testimony of Plaintiff's treating physician, Dr. West, as evidence of a manufacturing defect because Dr. West's belief the Durepair was defective was based on the fact the Durepair disintegrated. Specifically, Dr. West clarified in his deposition that he did not have any idea why the patch failed or that the patch was improperly manufactured.

Plaintiffs in their Reply to Defendants' Response reassert they did present sufficient evidence and did raise a genuine issue of material fact of a specific feature which made the product defective namely the fact that the Durepair disintegrated in Ms. Oglesby's body. Relying on *Ayres v. Sears, Roebuck & Co.*, 789 F.2d 1173, 1175 (5th Cir. 1985), Plaintiffs state the "Fifth Circuit has held that Plaintiffs have no burden to 'establish the specific feature which made the product defective.'" Reply, docket #168 at page 2. Here there is no dispute the Durepair patch disintegrated nor is there a dispute that the patch was not supposed to disintegrate. Plaintiffs also argue they are allowed to use

circumstantial evidence or *res ipsa loquitur* to show a manufacturing defect in this case because the adjustments or changes made to the patch were listed in the device's Instructions for Use and therefore, Defendants should not be allowed to argue that following the instructions negates the use of *res ipsa loquitur*.

In addition, Plaintiffs reassert Dr. Rasty provided enough evidence to raise a genuine issue of material fact as to a manufacturing defect. Plaintiffs argue further that:

> by dismissing Dr. Rasty's opinions because he "presented two equally likely causes of disintegration," and requiring Plaintiffs, at the summary judgment stage to establish a manufacturing defect "by a preponderance of the evidence," Magistrate Judge Bemporad is holding Plaintiffs to a higher burden than required at this stage. Summary judgment only requires Plaintiffs to demonstrate the existence of a fact question, it does not require Plaintiffs to show a manufacturing defect by a preponderance of the evidence. *See* Doc. 161, p. 6.
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> Further, Defendants wholly failed to address the fact that Magistrate Judge Bemporad's conclusion is free from any legal authority that would support the premise that an expert must only present one likely cause. In fact, by comparing the "two equally likely" causes and coming to the conclusion that there is no manufacturing defect by a preponderance of the evidence, the Magistrate Judge impermissibly weighed evidence rather than considering Plaintiffs' evidence in the best light. *Kennett-Murray Corp. v. Bone*, 622 F.2d 887, 892 (5th Cir. 1980) ("…the district court must not resolve factual disputes by weighing conflicting evidence…since it is the province of the jury to assess the probative value of the evidence.") (internal citations omitted).
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> In *Honea* [*v. Coca Cola Bottling Co.*, 183 S.W.2d 968 (Tex. 1944)],[1] in dealing with the quantum of proof required to discharge the plaintiff's burden in such cases, the Texas Supreme Court quoted from *Escola v. Coca Cola Bottling Co.*, 24 Cal.2d 453, 150 P.2d 436 (Cal. Sup. Ct. 1944) as follows:
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> > **It is not necessary, of course, that plaintiff eliminate every remote possibility of injury to the bottle after defendant lost control, and the requirement is satisfied if there is evidence permitting a**

[1] Although Plaintiffs merely cited the Court to "*Honea*" in its Reply, the Court was able to locate the case of *Honea v. Coca Cola Bottling Co*, as set forth above and was able to locate the quotation set forth therein.

> **reasonable inference that it was not accessible to extraneous harmful forces and that it was carefully handled by plaintiff or any third person who may have moved or touched it**.… If such evidence is presented, the question becomes one for the trier of fact … and, accordingly, the issue should be submitted to the jury under proper instructions.

See Escola,[2] 183 S.W.2d 970 (internal citations omitted)(emphasis added); *see also Benkendorfer v. Garrett*, 143 S.W.2d 1020, 1023-1024 (Tex. Civ. App.—San Antonio, 1940, writ dism'd). Magistrate Judge Bemporad erred and arguably abused his discretion in failing to follow well established precedent and imposing a burden—proof by a preponderance of the evidence—at the summary judgment stage of this litigation.

Reply, docket #168 at pages 3-4.

In their Conclusion, Plaintiffs maintain, in part, that "Defendants' hired experts say that Defendants did nothing wrong. Plaintiffs' experts opine that the only logical conclusion as to the cause of the device's disintegration is that it contained a manufacturing defect. This demonstrates the existence of a fact question that should preclude summary judgment and be resolved by a jury." Reply, docket #168 at page 5. The Court disagrees.

Despite Plaintiffs' contention above, the record does not reflect that the only logical conclusion as to the cause of the disintegration was a manufacturing defect. In fact, Plaintiffs' expert Dr. Rasty opined as to the possibility of at least two logical conclusions. In his deposition, Dr. Rasty testified as follows:

> Q. And I'm going to jump down to your conclusions on 7 Paragraph 33. We're looking at Section VIII called conclusions and opinions. Do you see that?
>
> A. Yes.
>
> Q. And what you say here in Paragraph 33 of Exhibit 1is that you, therefore, concluded that within a reasonably degree of engineering and scientific probability, and on a

[2] The Court presumes the Plaintiff intended to cite *Honea* here and not *Escola*.

more-likely-than-not basis, the subject Durepair contained a manufacturing defect and/or reacted adversely with the Adherus sealant which led to its disintegration as noted by Dr. West. Did I read that correctly?

A. You did.

Q. So, your conclusion, to a reasonable degree of engineering and scientific probability, that it was either a manufacturing defect or an adverse reaction with the sealant or both, correct?

A. Correct.

Q. So, we can understand that you're unable to rule out to a reasonable degree of scientific and engineering certainty that the CSF leak in this case was caused by an adverse reaction with the sealant, correct?

A. You are going to have to repeat that for me one more time, please.

Q. Based upon your conclusion here as it's stated in Paragraph 33, you're unable to rule out to a reasonable degree of engineering and scientific probability that the CSF leak in this case was caused by an adverse reaction with the sealant, correct?

A. Yeah. It's either one or the other or both in combination.

Q. Okay. And accordingly you're also unable to rule out to a reasonable degree of scientific certainty that the CSF leak in this case was caused by a manufacturing defect alone, correct?

A. I'm not able to say that it was definitively manufacturing defect. But it was either manufacturing defect or adverse reaction with the sealant.

Q. So, it could be a manufacturing defect, it might be an adverse reaction to the sealant, or both, correct?

A. Yeah. I mean, manufacturing defects you have to remember that a -- it's not a -- kind of like a light switch that is either on or off. You could have a manufacturing weakness and then combined with another adverse environment that causes that weakness to manifest into a failure where in the absence of that adverse environment that weakness would, have just remained a weakness without manifesting into a failure.

Q. And I understand what you're saying but given the evidence in this case that you reviewed and relied upon, you're unable to say that it was a manufacturing defect alone?

> A. Manufacturing, there's evidence that, you know, there are -- you know, as I've noted in my report, that it is a possibility that definitely some of the Durepairs in the lot that was manufactured are within -- very close to the bottom range of the tolerable thickness. So, if there was one that was close to that end, it would be weaker. And then you have this sealant that, according to the literature, causes adverse effects, then the two together could have caused the disintegration. The bottom line is that this thing is not designed to disintegrate like it did. And it either has to be a manufacturing weakness or defect, whatever you want to call it, combined with adverse reactions that are noted in the literature caused by the sealant. So, one or the other or in combination. It's hard to say which one definitively but it's one or the other in combination, more likely, in my opinion, the combination of the total disintegration of the device at issue.

July 11, 2022 Deposition of Jahan Rasty, Ph.D., docket #167-1 at pages 27-29. At page 30 of his deposition, Dr. Rasty was asked to make the record clear during this colloquy:

> Q. (BY MR. CHRISTIAN) Just so the record is clear, based upon your conclusions and opinions in this case, you can't say within a reasonable degree of engineering and scientific probability on a more-likely-than-not basis that the subject Durepair contained a manufacturing defect that caused this outcome alone?
>
> A. I've not –
>
> Q. Sorry. Go ahead.
>
> A. No. I've identified manufacturing weaknesses that could have potentially been at issue. But not having the device, not knowing exactly what its thicknesses were, I'm not able to say definitively whether a manufacturing defect by itself was the sole cause of the failure.

Id. at page 30. Although circumstantial evidence can support an inference that a product was defective, the evidence must "'do more than raise the possibility the injury could have resulted from a defect.'" *AIG Europe Ltd. v. Caterpillar Inc.*, Civil Action No. 1:17-CV-319, 2019 WL 8806217, at *15 (E.D. Tex. Oct. 3, 2019) (quoting *Shaun T. Mian Corp. v. Hewlett-Packard Co.*, 237 S.W.3d 851, 863 (Tex. App.–Dallas, Oct. 8, 2007, pet. denied)). While the evidence is not required to "'disprove all other possible causes for the injury . . . the likelihood of other possible causes must be so reduced that the fact-finder could reasonably find by a preponderance of the evidence that the cause

of the product failure lies at the manufacturer's door.' *Id.; see Casey* [*v. Toyota Motor Engr. & Mfg. N.A., Inc.*], 770 F.3d [332] at 326 [(5th Cir. 2014)] ('To prove a manufacturing defect under Texas law, a specific defect must be identified by competent evidence and other possible causes must be ruled out.')." *Id.* Here the Defendants have provided competent evidence that the sealant applied to the Durepair was an equally possible cause of the disintegration which has not been ruled out. Moreover, Plaintiffs' reliance on *res ipsa loquitur* fails in this case because "'Texas law does not generally recognize a product failure or malfunction, standing alone, as sufficient proof of a product defect,'" and the Fifth Circuit Court of Appeals has "explained that merely 'rel[ying] on *res ipsa loquitur'* is not a valid substitute for shouldering the burden of specifying a manufacturing defect." *Harrison v. Medtronic, Inc.*, No. 22-10201, 2022 WL 17443711, at *2 (5th Cir. Dec. 6, 2022) (the court noted in a footnote that "[*r*]*es ipsa loquitur* is also a poor fit here because it only applies when the product is in the 'control of the defendant.' Harrison pleads that his doctor, not Medtronic inserted the pacemaker, conceding the device was outside Medtronic's control when it allegedly malfunctioned."); *see Norman v. Bodum USA, Inc.*, 44 F.3d 270, 272 (5th Cir. 2022) (recognizing plaintiff must prove "the product was defective when it left the hands of the manufacturer and that the defect was a producing cause of the plaintiff's injuries"; also recognizing that product failure alone will "not generally suffice to prove a manufacturing defect; instead plaintiffs must "allege a specific deviation from the product's intended design that allegedly caused the injury"); *Brown v. Parker-Hannifin Corp.*, 919 F.3d 308, 312 (5th Cir. 1990) ("Without some basis to establish that one of his theories is the most likely cause of the failure on this occasion, [the expert's] testimony amounts to speculation and is no assistance to the jury."). Accordingly, Plaintiffs' objections are overruled.

The Court has reviewed the Plaintiffs' objections and conducted a de novo review of those issues raised by the Plaintiffs. The Court finds, after careful consideration of the record and the Report and Recommendation, that the objections lack merit. The Court hereby accepts, approves, and adopts the Magistrate Judge's factual findings and legal conclusions contained in the Report and Recommendation (docket #161), incorporates herein the arguments and authorities presented by the Defendants in their Joint Response to Plaintiffs' Objections (docket #167), and in their motions for summary judgment (docket numbers 104 and 105) and corrected replies in support of the motions for summary judgment (docket numbers 127 and 128), and finds the recommendation should be accepted such that Defendants Medtronic, Inc.'s and Medtronic USA, Inc.'s Motion for Summary Judgment (docket #104) and Defendant Integra Lifesciences Corporation's Motion for Summary Judgment (docket #105) shall be GRANTED and this case DISMISSED.

Accordingly, IT IS HEREBY ORDERED that the Report and Recommendation of United States Magistrate Judge, filed in this case on January 6, 2023 (docket #161), is ACCEPTED such that Defendants Medtronic, Inc.'s and Medtronic USA, Inc.'s Motion for Summary Judgment (docket #104) and Defendant Integra Lifesciences Corporation's Motion for Summary Judgment (docket #105) are GRANTED such that Plaintiffs' claims and this case are DISMISSED WITH PREJUDICE. Motions pending, if any, are also DISMISSED, and this case is now CLOSED.

It is so ORDERED.

SIGNED this 30th day of March, 2023.

FRED BIERY
UNITED STATES DISTRICT JUDGE